



California
Department of
Health Services

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June 20, 2005

CHDP Provider Information Notice No.: 05-07
CLPP Provider Information Notice No.: 2005-A

TO: ALL CHILD HEALTH AND DISABILITY PREVENTION (CHDP) PROGRAM PROVIDERS AND MEDI-CAL MANAGED CARE PLANS

SUBJECT: LEADCARE BLOOD LEAD TESTING SYSTEM RECALL, IMPACT ON CHDP PROVIDERS ORDERING RETESTS FOR BLOOD LEAD AND REVIEW OF CHDP CLAIMING AND REPORTING

The purpose of this Provider Information Notice is to:

- advise CHDP providers of a recall by ESA Biosciences (ESA), makers of the LeadCare Blood Lead Testing System
- alert providers that they may be contacted by a laboratory that uses the LeadCare Blood Lead Testing System requesting that the provider retest patients known to their practice
- review CHDP claiming and reporting for repeat blood lead tests.

Background

ESA Biosciences has issued a recall of LeadCare Test Kits shipped between September 2003 and April 2005 that have resulted in under reporting of blood lead levels (BLLs) by an average of 26 percent as compared to the graphite furnace atomic absorption spectroscopy method. In some instances, measurement of BLLs may have been as much as 40 percent below the actual level, so that individuals with a BLL measurement of six micrograms per deciliter ($\mu\text{g}/\text{dL}$) may actually have had an elevated BLL of 10 $\mu\text{g}/\text{dL}$ or an elevated BLL may have been under reported. ESA is voluntarily recalling and replacing the affected test kits.

Any laboratories using the defective kits have been asked to stop doing so immediately. They were recommended to retest all patients that previously were tested with one of the affected kits and in which an elevated blood lead level may have been missed or under reported, if they were not subsequently retested by a method other than LeadCare. The Childhood Lead Poisoning Prevention Branch (CLPPB) is contacting these laboratories to verify the laboratory's use of the LeadCare Testing System.

Laboratories Using LeadCare Contact of CHDP Providers

The CLPPB and the Occupational Lead Poisoning Prevention Program are asking the laboratories that use the LeadCare Blood Lead Testing System and the LeadCare Test Kit with a recalled lot number obtained between September 2003 and the present, to create a list of all individuals who were tested with one of the defective kits, had a blood lead result of equal to or greater than six µg/dL, and were not retested using another method. The laboratories are being asked to send a letter to the patient's healthcare provider advising the provider to have the test redone.

Ordering, Claiming and Reporting the Recheck of Blood Lead Test

CHDP health assessment providers may be asked to order a repeat blood lead test to assure that the results reported using the LeadCare Test Kit did not miss or under report an elevated blood lead level. If this occurs, use the following instructions.

If the provider orders the blood lead test, provides lead counseling, and draws the blood lead specimen

- complete the CHDP Confidential Screening/Billing Report (PM 160) as a partial screen, **and**
- enter CHDP code 23 on the first blank line of the Other Tests section of the PM 160, **and**
- enter either a check mark (✓) in outcome column A or an appropriate numeric follow-up code in outcome column C and/or D, **and**
- claim \$18.76 in the Fees Column if the patient is a Fee-for-Service beneficiary and CHDP services are being claimed and reported on a Standard or Regular PM 160 (Green form), **or**

- leave blank if the CHDP services are being claimed and reported on an Information Only PM 160 (Brown form), **and**
- write “Elevated Lead Level” in the “Comments/Problems” area, **and**
- include on laboratory request for analysis the comment “Recall Specimen.”

If the provider orders the blood lead test, provides lead counseling, and refers for blood drawing

- complete the CHDP Confidential Screening/Billing Report (PM 160) as a partial screen, **and**
- enter CHDP code 24 on the first blank line of the Other Tests section of the PM 160, **and**
- enter either a check mark (✓) in outcome column A or an appropriate numeric follow-up code in outcome column C and/or D, **and**
- claim \$0.00 in the Fees Column if the patient is a Fee-for-Service beneficiary and CHDP services are being claimed and reported on a Standard or Regular PM 160 (Green form), **or**
- leave blank if the CHDP services are being claimed and reported on an Information Only PM 160 (Brown form), **and**
- write “Elevated Lead Level” in the “Comments/Problems” area, **and**
- include on laboratory request for blood drawing and analysis the comment “Recall Specimen.”

Thank you for your participation in this effort to assure that elevated blood lead levels in children in California are measured accurately.

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If you have questions or concerns regarding the recall, please contact Leah Teitler, at the CLPPB, at (510) 622-4878 or LTeitler@dhs.ca.gov. For any questions or concerns regarding CHDP claiming and reporting processes, please contact your local CHDP program.

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